

**Notice of Allowability**

Application No.

10/089,287

Examiner

Blessing M. Fubara

Applicant(s)

LABARRE ET AL.

Art Unit

1618

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to telephonic interview with applicants' attorney on 10/13/05.
2. ☒ The allowed claim(s) is/are 2-11, 13-21 and 28-31 (claims are renumbered).
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All    b) ☐ Some\*    c) ☐ None    of the:
  1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  5. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08),  
Paper No./Mail Date \_\_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit  
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413),  
Paper No./Mail Date 10/13/05.
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_.

**THURMAN K. PAGE, M.A., J.D.**  
**SUPERVISORY PATENT EXAMINER**

### **DETAILED ACTION**

The Appeal brief is received and considered. Upon further consideration, claim 31, incorporating the cross-linking agent limitation of claim 12, which requires the formation of the copolymer before the cross-linking step would be allowable.

### **EXAMINER'S AMENDMENT**

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Charles Muserlian on 10/13/05.

The application has been amended as follows:

#### **Claim 1 (canceled)**

#### **Claim 2 (currently amended)**

A copolymer of claim [1] 31, wherein the polysaccharide is non-polycarboxylic.

#### **Claim 3 (previously presented)**

A copolymer of claim 2 wherein the non-cross-linked non-polycarboxylic polysaccharide is selected from the group consisting of agarose, agarpectin, amylose, amylopectin, arabinogalactan, carrageenans, cellulose, methylcellulose, chitosan, dextran, keratan sulfate, fucans and fucoidans, tragacanth, arabic, locust bean, guar gums and pullulan.

#### **Claim 4 (currently amended)**

A copolymer of claim [1] 31 wherein the polysaccharide is polycarboxylic.

**Claim 5 (previously presented)**

A copolymer of claim 4 wherein the polycarboxylic polysaccharide is selected from the group consisting of glycosaminoglycans, pectinic and alginic acid.

**Claim 6 (previously presented)**

A copolymer of claim 4 wherein the polycarboxylic polysaccharide is glycosaminoglycane selected from the group consisting of hyaluronic acid, chondroitin sulfate, heparin, dermatan sulfate and heparin sulfate.

**Claim 7 (currently amended)**

A copolymer of claim [1] 31 wherein the non-saccharidic polymer is non-polycarboxylic.

**Claim 8 (previously presented)**

A copolymer of claim 7 wherein the non-polycarboxylic non-saccharidic polymer is selected from the group consisting of poly(vinyl acetate), poly(vinyl alcohol), poly(acrylic esters), poly(methacrylic esters), poly(methacrylamines) and poly(acrylamides).

**Claim 9 (previously presented)**

A copolymer of claim [1] 31 wherein the non-saccharidic polymer is polycarboxylic.

**Claim 10 (previously presented)**

A copolymer of claim 9 wherein the non-saccharidic polymer is a polycarboxylic acrylic polymer.

**Claim 11 (previously presented)**

A copolymer of claim 10 wherein the polycarboxylic acrylic polymer is poly(acrylic acid) or poly(methacrylic acid).

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**Claim 12 (canceled)**

**Claim 13 (currently amended)**

A copolymer of claim [12] 31 wherein the cross-linking agent is a diamine.

**Claim 14 (currently amended)**

A copolymer of claim [1] 31 wherein the polysaccharide is degradable by the microbial flora of the colon.

**Claim 15 (previously presented)**

A copolymer of claim 14 wherein the polysaccharide is selected from the group consisting of chondroitin sulfate, hyaluronic acid, pectinic acid, heparin, dextran, chitosan, amylose, pectin, alginates and xanthan.

**Claim 16 (previously presented)**

A copolymer of claim 15 wherein the polysaccharide is chondroitin sulfate, and the non-saccharidic polymer is poly(acrylic acid) or poly(methacrylic acid), and the cross-linking agent is hexanediamine.

**Claim 17 (currently amended)**

A process for the preparation of cross-linked copolymers of claim [1] 31 comprising reacting said two separate non-cross-linked polycarboxylic copolymers in an aqueous medium in the presence of an activator of said cross-linking agent.

**Claim 18 (previously presented)**

The process of claim 17 wherein the activator is selected from the group consisting of carbodiimides, quinoline derivatives and mixed anhydrides.

**Claim 19 (currently amended)**

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A process for the preparation of non-cross-linked copolymers of claim [1] 31, comprising grafting the monomer of the non-saccharidic polymer onto the polysaccharide in an aqueous medium, under an inert atmosphere and in the presence of a catalyst which monomer will then polymerize under these reaction conditions.

**Claim 20 (currently amended)**

A pharmaceutical composition containing at least one active ingredient and, as an inert support or excipient, at least one cross-linked copolymer of claim [1] 31.

**Claim 21 (previously presented)**

A pharmaceutical composition containing at least one active ingredient and, as an inert support or excipient, at least one copolymer of claim 14.

**Claims 22 to 27 (cancelled)**

**Claim 28 (currently amended)**

A method of treating a disease of the colon in warm-blooded animals comprising administering to warm-blooded animals in need thereof an effective amount of an active colon treating ingredient with an excipient of at least one copolymer of claim [1] 31 for sustained release.

**Claim 29 (previously presented)**

The method of claim 28 wherein the active ingredient is absorbed at the colon level.

**Claim 30 (currently amended)**

The method of claim [30] 28 wherein the active ingredient is released in the upper parts of the digestive tract.

**Claim 31 (currently amended)**

A cross-linked copolymer prepared from a reaction between at least one non-cross-linked polysaccharide and at least one non-polysaccharide non-cross-linked polymer to link the two by a covalent bond to form a non-cross-linked polycarboxylic copolymer and reacting the latter with a cross-linking agent selected from the group consisting of diamines, natural and synthetic amino acids and polyamides to form a cross-linked copolymer, at least one of the polysaccharides or non-cross-linked polymer being polycarboxylic.

*Allowable Subject Matter*

2. The following is an examiner's statement of reasons for allowance: The closest prior art EL et al. (WO 98/08897) discloses cross-linked copolymers formed from non cross-linked polycarboxylic polymers and cross-linking agents that have at least two amine functions. However, El's process involves adding the non cross-linked polymers with the cross-linking agent in one port before the formation of the copolymer between the non-cross-linked polymers. In the instant case, a non-cross-linked co-polymer is formed between the non-cross-linked polysaccharide and the non-cross-linked non-polysaccharide moieties before the cross-linking agent is added to the non-cross-linked copolymer to form the cross-linked co-polymer. Thus, the pending claims as amended are allowable.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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